William H. Ingaldson
Peter A. Sandberg
Ingaldson Fitzgerald, P.C.
813 W. 3rd Avenue
Anchorage, Alaska 99501
bill@impc-law.com
peters@impc-law.com
Telephone (907) 258-8750
Fax (907) 258-8751
Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

MICHAEL JAMES WHITE, and BECKY ANN WHITE Plaintiffs, v. ZIMMER, INC., a Delaware corporation, ZIMMER HOLDINGS, INC and ZIMMER, U.S, INC. Defendant.	Case No. ~~3:civ-19-~~ 3:19-cv-00161-SLG

COMPLAINT

Comes now Plaintiffs, Michael James White, and Becky Ann White, by and through their counsel of record, Ingaldson Fitzgerald, P.C., and asserts as follows:

PARTIES

1. Plaintiff, Michael James White, is, and at all relevant times to this claim was a resident of Anchorage, Alaska.

2. Plaintiff, Becky Ann White is the wife of plaintiff Michael James White, is, and at all relevant times to this claim was a resident of Anchorage, Alaska.

INGALDSON, FITZGERALD, P.C.
Lawyers
813 W. 3rd Avenue
Anchorage, Alaska
99501-2001
(907) 258-8750
FAX: (907) 258-8751

3. Defendant, Zimmer, Inc., Zimmer Holdings, Inc, and Zimmer USA, Inc. (hereinafter collectively "Zimmer" or" Defendants") are corporations, incorporated in the State of Delaware with their principal place of business in the State of Indiana, and at all times material hereto, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the Defective Products under the name "Chrome Cobalt femoral head" either directly or indirectly, to members of the general public within the State of Alaska, including to plaintiff.

JURISDICTION AND VENUE

3. Defendant Zimmer, is a Delaware corporation with its principle place of business located at 345 East Main Street, Warsaw, Indiana, and conducts business throughout the United States, including the State of Alaska by developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, selling, and/or otherwise placing into the stream of commerce hip replacement components including the M/L Taper femoral stem in a manner reasonably calculated to reach and impact the general public in the State of Alaska, including Plaintiffs.

4. Venue is proper in this Court under Diversity in that at present and at all material times relevant to this action Zimmer is an Indiana Corporation and committed a tort in whole or in part in the State of Alaska.

5. This Court has subject matter jurisdiction because the Defendant does business in the State of Alaska, and the harm caused by the Defendant to Plaintiff occurred in the State of Alaska.

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FACTUAL ALLEGATIONS

6. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution and sale of Zimmer's defective hip components, the "M/L Taper hip prosthesis with Kinectiv Technology femoral stem". At all times relevant to this Complaint, Zimmer regularly engaged in business in the State of Alaska.

7. At all times relevant to this Complaint, Zimmer placed the "M/L Taper hip prosthesis with Kinectiv Technology femoral stem" components as part of their "Hip Joint Replacement System components" (hereinafter "Defective Products") into the stream of interstate commerce.

8. At all relevant times, Zimmer expected or should have expected that its acts and omissions would have consequences within the United States, and the State of Alaska.

9. Plaintiffs' damages in this matter accrued in the State of Alaska.

THE DEFECTIVE DEVICES: "VERSYS CHROME COBALT FEMORAL HEAD" " M/L TAPER HIP PROSTHESIS with KINNECTIV TECHNOLOGY" "Hip Joint Replacement System components"

10. Total hip arthroplasty, commonly referred to as hip replacement surgery, is the term used to describe the surgery wherein a patient's natural hip anatomy is replaced with synthetic components. A patient may need a total hip arthroplasty for a variety of medical reasons including degenerative bone disease and avascular necrosis.

11. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The

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acetabulum is the cup shaped socket portion of the hip and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

12. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal, plastic, or ceramic. A total hip replacement typically consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head is usually a metal or ceramic ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic or ceramic acetabular liner that is attached to the interior portion of the metal acetabular shell comprised of metal on its outer surface. When complete, the femoral stem anchors the femoral head that rotates within the acetabular liner sitting inside the acetabular shell. Historically, femoral heads were not made with chrome and cobalt.

13. At all times material hereto, the Zimmer Defendants developed, designed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, promoted, marketed, supplied, sold and/or warranted the Defective Devices either directly or indirectly, to members of the general public throughout the United States and the State of Alaska, including to Plaintiff.

14. The Defective Devices are modular femoral hip replacement devices to be used in total hip replacement surgery. They are indicated for patients requiring primary total hip arthroplasty due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis including osteoarthritis and avascular necrosis.

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15. As noted, the Defective Devices are critically different from most traditional femoral heads used in total hip replacements because they consist of two basic modular components: a chrome cobalt head component that is inserted into offset M/L taper stem and then into an acetabular shell.

16. The defective design and manufacture of the Defective Devices allows fretting and corrosion to occur at the Morse taper junctions between the femoral head and M/L taper stem, and the liner of the hip replacement components. The fretting and corrosion allows metal ions, including cobalt and chromium, to be released into the surrounding tissues. The fretting and corrosion and release of ions also manifest in increased cobalt and chromium blood levels of the patient. These cobalt and chromium ions destroy surrounding tissue and bone often causing pseudotumors and a condition called metallosis.

FACTUAL ALLEGATIONS

17. Prior to September 8, 2012, defendant Zimmer manufactured the following components:

a. A Zimmer 36 MM XLPE Liner, Model Number 8751-12-36; Lot Number 62033830;

b. A Zimmer 56MM Acetabular Shell, Model Number 8757-056-011; Lot Number 6206492;

c. A size R2 M/L Taper Stem hip prosthesis with Kinectiv Technology Model Number 00-7848-042-01, Lot Number 62053330;

INGALDSON, FITZGERALD, P.C.
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d. A VerSys Chrome Cobalt femoral Head 36 MM, Model Number 00-8018-36-02, Lot Number 62122125;

e. A Zimmer Femoral Stem Model Number 00-7713-011-00; Lot Number 62030077.

These components, hereinafter referred to as "Defective Products" were surgically implanted in Mr. White's right hip by Dr. Jeffrey S. Moore on September 8, 2012 at Alaska Regional Hospital in Anchorage, Alaska.

18. Following his surgery, Mr. White followed his physician's orders, and returned for follow up care as ordered. He began having significant pain in his right hip in 2014. He followed up with his surgeon, but was told that there was nothing that could be done.

19. Mr. White was experiencing symptoms related to metallosis, including pain in his hip area, cardiac issues, and a distressing cognitive dysfunction. He was seen on February 26, 2019 by Dr Stephen Tower, and was evaluated for cobalt in his blood and urine. His urine screening found levels of 30ppb and radiology demonstrated the presence of fluid in his hip joint. Based on those findings, Mr. White was advised to have right hip revision surgery.

20. On May 9, 2019, Mr. White underwent a revision surgery for his right hip with Dr Stephen Tower at Alaska Regional Hospital in Anchorage, Alaska. Dr. Tower found significant symptoms of metallosis corrosion in his right hip, including a pseudo tumor and tissue necrosis.

INGALDSON, FITZGERALD, P.C.
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21. At all material times, Zimmer failed to disclose to the FDA, healthcare professionals, consumers, or Plaintiff, the information it possessed concerning the defective nature of the "Hip Joint Replacement System" and the actual adverse medical events, injuries and need for replacement surgery suffered by patients. Instead, upon information and belief, Zimmer actively promoted the "Hip Joint Replacement System" for patients without informing them of the dangers of Cobalt/ Chromium metallosis.

22. At all material times, Zimmer concealed information about pain and suffering following insertion of the "Defective Products" and the need for replacement surgery.

23. At all material times, the "Defective Products" manufactured and/or supplied by Zimmer, was unaccompanied by proper warnings regarding all possible adverse consequences and the alarming rate of failure of the aforesaid product and the need for replacement surgery.

24. As a direct and proximate result of Zimmer placing the Defective Products into the stream of commerce, plaintiff Michael James White has suffered and continues to suffer both injuries and damages in the State of Alaska, including but not limited to: past, present, and future physical and mental pain and suffering; and past, present and future medical, hospital, monitoring, rehabilitative expenses.

25. As a direct and proximate result of Zimmer placing the Defective Products into the stream of commerce, plaintiff Becky Ann White has suffered and continues to suffer both injuries and damages in the State of Alaska, including but not limited to: loss of consortium and loss of companionship.

INGALDSON, FITZGERALD, P.C.
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CAUSES OF ACTION
COUNT I
(STRICT PRODUCT LIABILITY)

26. Plaintiffs incorporate by reference, paragraphs 1 through 25 above, as if fully set forth herein.

27. At all times material hereto, Zimmer engaged in the business of developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, retailing, supplying and/or selling the Defective Products and through that conduct placed the Defective Products into the stream of commerce in the State of Alaska.

28. The Defective Products were defectively designed and/or manufactured so as to be unreasonably dangerous to consumers.

29. The Defective Products were intended for use in hip replacement procedures for consumers. Mr. White became a consumer and relied upon the safety of Defendant's product.

30. Zimmer failed to warn the public, including Mr. White, of the risk of suffering the type and manner of injuries suffered by Mr. White, which risks and/or dangers were known or should have been known to Zimmer.

31. Zimmer expected its Defective Products to reach, and it did in fact reach, consumers in the State of Alaska, including Mr. White, without substantial change in its condition.

INGALDSON, FITZGERALD, P.C.
Lawyers
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99501-2001
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32. Zimmer knew and intended that its Defective Products would be purchased from Zimmer by members of the general public and would be used by such purchasers without any inspection for defects.

33. As a direct and proximate result of the defective and unreasonably dangerous condition of the Defective Products, Mr. White sustained injuries and damages which will be proven with more specificity at trial.

COUNT II
(BREACH OF EXPRESS AND IMPLIED WARRANTIES)

34. Plaintiff incorporates by reference, paragraphs 1 through 33 above, as if fully set forth herein.

35. At the time and place of the sale, distribution and supply of the Defective Products to Plaintiff, Zimmer expressly represented and warranted that its product was safe, and impliedly warranted that the product was reasonably fit for its intended purpose and was of marketable quality.

36. Zimmer's Defective Products were unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said product, and accordingly Defendant breached both express and implied warranties.

37. As a direct and proximate result of Zimmer's breach of warranty, Mr. White sustained injuries and damages which will be proven with more specificity at trial.

COUNT III
(NEGLIGENCE)

INGALDSON, FITZGERALD, P.C.
Lawyers
813 W. 3rd Avenue
Anchorage, Alaska
99501-2001
(907) 258-8750
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38. Plaintiffs incorporate by reference, paragraphs 1 through 37 above, as if fully set forth herein.

39. Zimmer was under a duty to use reasonable care in the design, manufacture, and the provision of warnings accompanying the Defective Products.

40. Zimmer was under a duty of care in the distribution and sale of its Defective Products so that they would be reasonably safe for their intended use.

41. Zimmer breached this duty by, among other things:

a. Failing to exercise care in designing, developing, manufacturing, retailing, distributing and selling its Defective Products so as to avoid the above risks to individuals using the product;

b. Failing to include adequate warnings with its Defective Products which would alert Plaintiff and other consumers to its potential risks and serious side effects;

c. Failing to adequately and properly test its Defective Products before placing them into the stream of commerce;

d. Failing to conduct sufficient testing on its Defective Products, which if properly performed, would have shown that the products had serious side effects, including, but not limited to, loosening and causing pain and discomfort in the hip;

e. Failing to provide adequate post-marketing warnings or instructions after Zimmer knew, or should have known, of the significant risks of injuries and events from the use of the Defective Products.

INGALDSON, FITZGERALD, P.C.
Lawyers
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42. As a direct and proximate result of Zimmer's negligence, Mr. White sustained injuries and damages which will be proven with more specificity at trial.

COUNT IV
(MISREPRESENTATION)

43. Plaintiff incorporates by reference, paragraphs 1 through 42 above, as if fully set forth herein.

44. At all relevant times, Zimmer represented to Plaintiff directly and/or through their agents, servants and representatives, that the Defective Products were fit for intended uses and would otherwise benefit users.

45. Zimmer made such representations, knowing they were false and that Plaintiffs would rely upon same.

46. Mr. White did, in fact, rely upon Zimmer's representation to his detriment.

47. Mr. White's reliance upon such statements was reasonable.

48. As a direct and proximate result of Zimmer's misrepresentations, Mr. White suffered injuries and damages which will be proven with more specificity at trial.

COUNT VI
(PUNITIVE DAMAGES)

49. Plaintiffs incorporate by reference, paragraphs 1 through 48 above, as if fully set forth herein.

50. Prior to the manufacturing, sale and distribution of the Defective Products, Zimmer knew, or was reckless in not knowing, that the products were in a defective condition and that those who were implanted with such devices were at an unreasonable risk of experiencing injury. Zimmer through its officers, directors and managing agents,

INGALDSON, FITZGERALD, P.C.
Lawyers
813 W. 3rd Avenue
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99501-2001
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had notice and knowledge from several sources, prior to the date of marketing and sale of the Defective Products to Mr. White, that the products presented a substantial and unreasonable risk of harm to the consumer, including Mr. White, and as such said consumers were unreasonably subjected to risk of injury from the use of those products.

51. Despite such knowledge, Zimmer, through its officers, directors and managing agents, knowingly and deliberately failed to remedy the known defects in its product and failed to warn the public, including Mr. White, of the serious risk of injury occasioned by the defects inherent in the Defective Products.

52. Upon information and belief, Zimmer's failure to notify the public, including Mr. White was for the purpose of increasing sales and enhancing their profits and Zimmer intentionally proceeded with manufacturing, selling and marketing of the Defective Products knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests.

53. The actions of Zimmer as noted herein were outrageous and demonstrated reckless indifference to the welfare of the intended users of the Defective Products, and was done so as to profit its own self-interests and as such warrant exemplary damages.

WHEREFORE, Plaintiff prays for the following relief:

1. For a judgment against Defendant Zimmer and in favor of plaintiff, and in an amount in excess of $250,000, the exact amount to be proven at trial;

2. For Exemplary Damages, prejudgment interest, punitive damages, costs and attorney's fees; and

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3. For such other and further relief as this court deems just and equitable.

RESPECTFULLY SUBMITTED this 3rd day of June, 2019.

INGALDSON FITZGERALD, P.C.
Attorneys for Plaintiffs

By: _____
Peter Sandberg
ABA No. 0611084

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INGALDSON, FITZGERALD, P.C.
Lawyers
813 W. 3rd Avenue
Anchorage, Alaska
99501-2001
(907) 258-8750
FAX: (907) 258-8751